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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,509	06/28/2001	Hiroaki Shizuya	CIT1390-1	8122

7590 05/05/2004

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/896,509	<b>Applicant(s)</b> SHIZUYA, HIROAKI	
	<b>Examiner</b> Maria B Marvich, PhD	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
    1. ☐ Certified copies of the priority documents have been received.  
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
    \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
    a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

This office action is in response to an amendment filed 2/11/04. Claims 1, 2, 14-16, 24, 25, 31 and 43 have been amended. Claims 1-55 are pending in this application.

#### ***Response to Amendment***

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by Applicant's Amendment of the claims, and therefore, this rejection is Non-Final.

#### ***Claim Objections***

Claim 1 is objected to because of the following informalities: in line 3, the abbreviation BAC appears without being defined. A second occurrence of BAC in line 6 is defined. It would be remedial to delete the definition in line 6 and add it to line 3. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1, 25 and 43 are vague and indefinite in that the metes and bounds of “artificial” are unclear. The phrase “which is capable of transformation by artificial means are unclear. Some cells are “naturally competent for transformation. It is unclear whether the transformation step practiced and the method is necessarily one where the cell has been made competent for transformation or else encompasses “naturally” competent cells. **This is a new rejection.**

The preamble of claims 1 indicates that the method is used for identifying an essential chromosomal gene. However, the method steps do not include any steps that relate back to this preamble. It would be remedial to include a step for the identification of essential genes. **This is a new rejection.**

Claim 3 and 9 are vague and indefinite in that the metes and bounds of “the identifying” are unclear. As claim 1 recites, “identifying” in two separate places, it is unclear to which “identifying” dependent claims 3 and 9 refer. **This is a new rejection.**

Claim 10 is vague and indefinite in that the metes and bounds of “selectively non-permissive” are unclear. It is unclear to what “selectively” is selective towards or against. It would be remedial to delete “selectively” from this claim. **This is a new rejection.**

Claim 14 recite the limitation "the identified chromosomal gene" in claim 1. There is insufficient antecedent basis for this limitation in the claim. There is no “identified essential chromosomal gene” in claim 1. It appears that the claim is referring to the “identified haploid cells” in claim 1. **This is a new rejection.**

Claims 14-16 are vague and indefinite in that the metes and bounds of “the known segment of DNA in the host cell” are unclear. There are two known segments of DNA that are in the host cell. It is unclear to which the claim refers- that of the haploid test

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organism or that of the chromosomal DNA in the host cell. Furthermore, it is unclear why "identified" has been deleted from claim 16. **This is a new rejection necessitated by applicant's amendment.**

Claim 24 recites the limitation "insertion into the merodiploid test cell" in claim 23. There is insufficient antecedent basis for this limitation in the claim. It would be remedial to recite "transformation of the haploid host cell". **This is a new rejection necessitated by applicant's amendment.**

Claim 25 is vague and indefinite in that the metes and bounds of "suitable" are unclear. The term "suitable" is a relative one not defined by the claim, no single set of conditions is recognized by the art as being "suitable" and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established. **This is a new rejection.**

Claim 25 is vague and indefinite in that the metes and bounds of "A method comprising" are unclear. The claim lacks a preamble and therefore it is unclear to what the method is drawn. **This is a new rejection necessitated by applicant's amendment.**

Claim 25 recites the limitation "in the haploid test cell" (line 19-20) in claim 25. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection necessitated by applicant's amendment.**

Claim 43 recites the limitation "in the haploid test cell" in claim 43. There is insufficient antecedent basis for this limitation in the claim. The BAC contains DNA from the haploid test organism which in previous claims is distinctly different from the haploid test cell. **This is a new rejection.**

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Claim 46 is vague and indefinite in that the metes and bounds of “introduction of the BAC into the test cell” are unclear. The BAC is not introduced into the test cell but is introduced into the haploid host cell. **This is a new rejection.**

Claim 47 recites the limitation “known segment of DNA is linearized prior to introduction into the test cell” in claim 46. There is insufficient antecedent basis for this limitation in the claim. The BAC, that comprises the known segment of DNA, but not the known segment of DNA is introduced into the haploid host cell. **This is a new rejection necessitated by applicant’s amendment.**

### *Response to Arguments*

Applicants discuss the rejections under 35 U.S.C. 112, second paragraph on pages 15-17 of the amendment filed 2/11/04. Applicants indicate that claim 25 has been amended to recite a clearer preamble. However, the amended changes are not found in the claim. The claim lacks a preamble and therefore it is unclear to what the method is drawn.

Applicants state that claim 24 has been amended to read “insertion into the merodiploid test cell” as there is antecedent basis in claims 1 and 23. Furthermore, applicants are unclear as to why use of the term “select” in claim 25 is unclear. While antecedent basis is found for recitation of “merodiploid test cell”, as indicated in the rejections above, the merodiploid test cells are not transformed, as they are the product of transformation. The haploid host cell is transformed with the BAC. As to use of the word “selecting”, the claim recited, “whose **genome** is known to select”. It was unclear how a **genome** can perform the function of selecting.

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*Conclusion*

No claims are allowed.

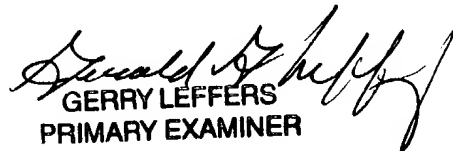
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

April 28, 2004

  
GERRY LEFFERS  
PRIMARY EXAMINER